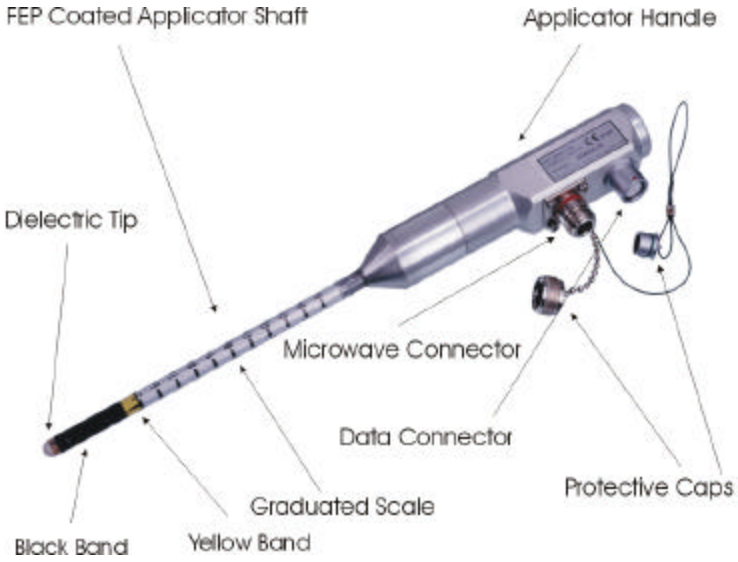
EXECUTIVE SUMMARY

Device Description

The Microwave Endometrial Ablation (MEA) system is a device designed to ablate the endometrial lining of the uterus for women experiencing heavy menstrual bleeding (menorrhagia) by distributing microwave energy throughout the uterine cavity via a hand held applicator. The absorption of microwave energy into a thin layer of tissue increases tissue temperature levels to 75-85? Celsius, resulting in a limited depth of coagulation. The physician controls the treatment by moving the applicator throughout the uterine cavity while monitoring treatment temperature on a real-time display. This control allows the physician to ensure that complete treatment of each region of the uterine cavity is achieved, regardless of variations in endometrial thickness or other irregularities of the uterus. Markings on the applicator shaft assist the physician in monitoring the overall treatment progression and provide a visual indication of when the treatment is complete, generally 3-5 minutes.



Pivotal Trial

MEA was initially evaluated versus surgical ablation (transcervical resection of the endometrial - TCRE) in a randomized controlled trial by the Aberdeen Royal Infirmary (Bain, C et al, Microwave Endometrial Ablation versus Endometrial Resection: A Randomized Controlled Trial, *Obstetrics & Gynecology*, June 2002), establishing both clinical efficacy and safety. This study showed that MEA is as effective as TCRE for the treatment of menorrhagia. There were no device related adverse events within this clinical evaluation. The protocols employed in the Aberdeen study were presented to the Food and Drug Administration (FDA) in support of a PMA pivotal trial, in accordance with the Thermal Endometrial Ablation Devices, Submission Guidance for an IDE Obstetrical and Gynecology Division Thermal Ablation Guidance Document. The FDA approved the Microsulis Investigational Device Exception (IDE) and the commencement of the pivotal trial occurred at 5 U.S. and 3 international sites.

The pivotal trial incorporated a 2:1 randomization scheme of MEA to rollerball endometrial ablation (REA) and enrolled 216 MEA patients, more than any previously evaluated PMA trial. The pivotal trial successfully demonstrated that MEA is as effective in treating patients with menorrhagia as the REA control group, and produced very high success and amenorrhea rates, both among the general study population and the fibroid population. Study success was defined as a reduction in bleeding diary score from 185 prior to treatment to 75 or less 12 months post treatment. An analysis of the Intent to Treat population shows that MEA resulted in 87.0% success in the MEA group, compared to the 83.2% within the REA group. Amenorrhea outcomes were 55.3% in the MEA group and 45.8% in the REA group.

There were no device related adverse events in the clinical study.

Scientific Validation

Microsulis has conducted specific bench tests validating the thermal heating effects and treatment monitoring functions of the MEA device. The testing occurred under worst-case conditions, that is, 60 minutes at 90 degrees centigrade with the applicator held in a static position. Although the applicator is not held in a static position during clinical use, the test results demonstrated a worst-case maximum thermal penetration depth of 7mm into uterine tissue.

Thermal modeling studies show that the tissue heating effects from microwave energy used for the purpose of thermal endometrial ablation is the same as those produced from other thermal endometrial ablation devices. The mechanisms of heat conduction into uterine tissue are the same regardless of the source of heating. This thermal penetration effect applies to both hydrothermal and electro-thermal energy sources.

Microsulis has validated a temperature rise gate (TRG), a temperature monitoring function to identify an abnormal temperature rise at the initiation of treatment.

Manufacturing Site Audit

Upon submission of the PMA application, the FDA conducted a pre-approval inspection of the manufacturing facility. The audit found no deficiencies.

Risk/Benefit Analysis

As occurred during the PMA trials for other approved devices, there were no device related adverse events associated with MEA during the PMA trial.

In over 6 years of commercial use of MEA involving more than 14,600 treatments administered by over 700 physicians, there have been some reports of adverse events. Microsulis and a panel of clinical experts have carefully investigated each report to determine the root cause of each adverse event. In each of these cases the MEA device was determined to have operated correctly, with no malfunctions

To minimize the potential risk of patient injury that may result from thermal ablation treatment, in particular, an injury that occurs in the absence of a uterine wall perforation, Microsulis employed the following factors in the PMA trial:

1. Ultrasound evaluation of the uterine wall in all patients to establish that no area is less than the minimum uterine wall thickness, and
2. Hysteroscopy to evaluate the uterine cavity in all patients prior to commencing treatment.

Over 1,400 consecutive commercial treatments have been performed since July 1996 at three hospitals (Centers for Excellence), each of which has been using treatment procedures and practices consistent with the IFU and training that is presented in the PMA. There have been no reported adverse events occurring during this time period. This demonstrates that the device is safe when used according to the IFU and training that is presented in the PMA labeling.

In conclusion, the high efficacy rates and the lack of adverse events achieved in the FDA clinical study and at the 3 commercial centers of excellence support the proposed labeling and approval of the MEA device.

PRODUCT PERFORMANCE - DESIGN VERIFICATION

REUSABLE APPLICATOR AND CONNECTORS

Non-clinical bench testing and animal testing have been conducted to demonstrate the safety, reliability and performance specifications of the MEA System. The following tests were conducted to verify the design of the reusable applicator and control module.

Microwave Connectors Pull Test: The "WW Fisher" and "N" type microwave connector that are attached to the microwave module and the applicator assembly were both subjected to standardized Pull Testing to verify that the connectors can withstand accidental pull forces up to 100 N. The testing demonstrated there were no visual signs of damage or deformation to the connectors due to the pull tests.

Applicator Useful Life: Functional testing was performed on the reusable hand-held applicator after repeated simulated uses (which included soiling, and cleaning and steam sterilization with standard procedures). The results of the tests demonstrate that MEA applicators remain functional after being subjected to 30 repeated uses.

Microwave Thermal Penetration Limit: Design testing of the MEA System and Applicator was conducted that validates the maximum depth of thermal penetration associated with the use of the MEA System. The testing demonstrates that worst-case thermal penetration is limited to 7 mm when a uterine blood perfusion of 15.8 (mL/100g/100min) is assumed.

MEA Applicator Shaft Temperature Testing: It was shown that applicator shaft temperature that is in contact with the patient will not rise above 40 ?C during a treatment and therefore concluded that there is no risk to the patient of exposure to excessive temperature rises from the shaft heating the cervix.

Temperature Rise Gate: Microsulis has validated a temperature rise gate (TRG), a temperature monitoring function to identify an abnormal temperature rise at the initiation of treatment.

Applicator Microwave Connector Leakage Testing: Far-field and near-field tests were carried out on the MEA applicator and N-type connector to provide assurance that the MEA applicator does not leak microwave energy at the surface and at distances less than 1 meter. The results of the testing demonstrate that the level of energy emitted from the MEA applicator is far below the safe limit specified for maximum continuous exposure as specified in IEEE C95.1. This confirms that there is no hazard to the clinician or the patient from far-field or near-field emissions from the MEA device.

Applicator Shaft Microwave Leakage Testing: Bench tests were conducted to confirm that the microwave energy radiation is confined to the tip of the applicator and not emitted along the entire length of the applicator shaft. A spatial peak value of SAR was determined using a polyacrylamide gel phantom. Testing of the SAR around the applicator shaft using two thermocouples located 1 mm from the applicators N-type connectors detected no hazardous levels of SAR as defined by IEEE C95.1 (<8W/kg).

ELECTRICAL & MECHANICAL SAFETY

Electromagnetic Compatibility

Electrical safety and electromagnetic compatibility testing was performed in accordance with internationally recognized standards by independent test facilities. Certification of Compliance and/or documentation of successful test results for the MEA System to the following standards were provided.

?? EN 60601-1: electrical safety,
?? IEC 60601-1-2: collateral standard, electromagnetic compatibility requirements of medical equipment,
?? IEC 801-2: electrostatic discharge,
?? IEC 801-3: radiated susceptibility,
?? IEC 801-4: fast transient bursts,
?? CISPR 11:990: radiated and conducted emissions,
?? CFR 47 Part 18: FCC industrial, scientific and medical radiated emissions and
?? CSA C22.2 601-1:Safety of medical equipment – part 1

SOFTWARE VALIDATION

In accordance with the requirements set forth in the FDA Guidance document entitled *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, the level of risk for the MEA System was considered to be **moderate**. The device hazard analysis provided takes into account the foreseeable hazards associated with the device's intended use, hardware and software and identifies the corrective measures taken to eliminate or reduce each hazard. Software documentation provided on the device system is consistent with its intended use, and the software level of concern and consists of the following:

?? Device hazard analysis,
?? Software description and requirements documents,
?? Architecture design chart,
?? Software traceability analysis, and
?? Software validation results

The software validations demonstrated that the device and the software contained within the device, perform in accordance with manufacturer's specification for the device to function safely and effectively.

MATERIAL SAFETY (TOXICOLOGY)

Biocompatibility/Toxicity Testing

In-vivo and *in-vitro* toxicity tests were conducted on the patient contacting materials of the reusable applicator that establish the biocompatibility of the device. The MEA applicator passed all testing which was conducted in accordance with the requirements of International Standard

ISO 10993: Biological Evaluation of Medical Devices, Part 1, and FDA's Good Laboratory Practices (GLP), 21 CFR 58, and included the following tests:

- ?? Cytotoxicity (ISO Elution, MEM)
- ?? Sensitization (ISO Maximization in the Guinea Pig)
- ?? Irritation (ISO Acute Intracutaneous Reactivity in the Rabbit)

The studies demonstrate that the patient contacting materials of the applicator is safe for use in a reusable medical device.

Sterility
The MEA applicator is not supplied sterile. It is designed to be cleaned and sterilized by the user prior to use. The steam sterilization instructions recommended in the device labeling was validated by an independent laboratory to AAMI guidelines (AAMI TIR No. 12, 1994) and provides a sterility assurance level (SAL) for the device of at least 10^{-6}.

EXCISED TISSUE STUDIES

Bench testing with *ex vivo* porcine livers was completed to verify the shape and depth of heating caused by the microwave energy provided through the applicator tip at 9.2GHz. Activation of microwave energy with the applicator completely surrounded by liver showed that a spherical uniform depth of coagulation, limited to 5-6 mm, was achieved.

EXCISED UTERI STUDY

In vitro tests were conducted using the microwave applicator on excised non-perfused and perfused uteri salvaged from routine hysterectomies to determine depth of necrosis, complete cavity coverage, serosal heating, and containment of all microwave energy in the uterine cavity. The endometrial cavities from 4 non-perfused excised uteri were ablated. During these tests the temperature in the endometrial cavity and on the uterine body was monitored. Microwave leakage measurements were made using a power meter. All specimens were sent to pathology after treatment to measure coverage of ablated area and depth of necrosis. The results of these tests showed that it was possible to destroy endometrial tissue throughout the uterine cavity to a limited depth of 5-6 mm without raising serosal uterine temperature levels.

Further experiments involved 8 excised perfused uteri. Temperature and microwave leakage measurements were made and the specimens were sent to pathology. The results of these tests indicated that blood perfusion did not effect the depth of the necrosis and it was possible to destroy endometrial tissue throughout the uterine cavity without raising serosal uterine temperature levels. These tests demonstrated that the physician could guide the applicator tip throughout the uterine cavity using tissue temperature measurements to control coverage of the ablation effect.

SUMMARY OF CLINICAL STUDIES

Pre-Hysterectomy Clinical Studies

In vivo tests using the microwave applicator for endometrial ablation on patients having a hysterectomy. *In vivo* tests were performed on 16 women prior to hysterectomy using various power levels. In each case thermocouples were positioned on the uterine serosal surface to confirm that no temperature rise occurs during treatment. Following treatment, hysterectomy was completed and uterine specimens were sent to pathology to determine overall ablation coverage and depth of necrosis.

Additional *in vivo* tests were completed on hysterectomy subjects to evaluate the same parameters at the design power of 30 watts to ensure no microwave leakage or serosal heating occurred.

The *in vivo* testing provided valuable data regarding patient safety, the MEA surgical procedure and the energy dose required to achieve a 5mm depth of destruction throughout the entire endometrial cavity. Internal uterine tissue necrosis was approximately 5-6 mm, while external serosal tissue and myometrium were undamaged.

A further test was performed on a pre-hysterectomy patient to measure the normal operative treatment forces that a physician exerts on the hand-held applicator and to also measure the *in vivo* forces required to perforate the uterine wall. A MEA applicator was fixed to a handgrip via a three-axis load cell device that measured the forces that the physician's hand applied to the applicator. These forces included the forward force applied while entering the cervix and the lateral forces applied while sweeping the applicator tip throughout the uterine cavity. A simulated MEA procedure was performed measuring the intraoperative forces. The MEA applicator was then reintroduced to demonstrate the force required for perforation of the uterine fundus. It was difficult to perforate the uterine wall, however, the physician was able to do so on the sixth attempt. The perforation occurred in the midline, on the postero-superior serosal uterine surface. The results of the testing showed that the insertion forces via the endocervical canal and lateral forces during the procedure never exceeded 1.5 Kg. The force required to perforate the uterine wall was measured to be about 9 Kg; 6 times greater that the force required to perform an MEA treatment.

FEASIBILITY & INTERNATIONAL CLINICAL STUDIES

Royal United Hospital, Bath.

Twenty-three patients were treated with MEA at 9.2 GHz and 30 W. The endometrium was thinned pre-operatively with Goserelin or Danazol four weeks prior to ablation treatment. Average age was 42.6 years (range 36-55). After six months, success rate (defined as amenorrheic or light menstruation) was 83%. Thirteen patients (57%) were amenorrheic, and six patients (26%) experienced light menstruation. Three unsuccessful patients with thick endometrium were retreated under the same protocol and were amenorrheic. Nineteen patients (95%) experienced an improvement in dysmenorrhea and 16 (80%) patients experienced complete relief.

Aberdeen Royal Infirmary, Aberdeen, Scotland

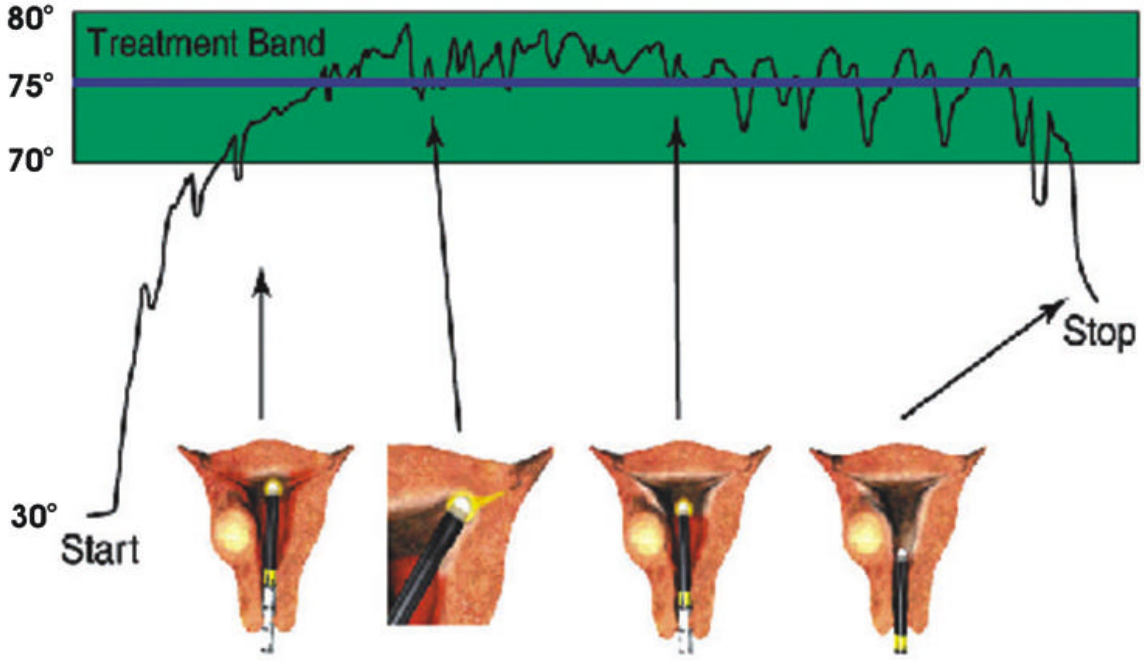
Microwave endometrial ablation (MEA™) was evaluated in a prospective, randomized controlled trial in order to evaluate the menstrual effect and surgical intervention rate after treatment compared to transcervical endometrial resection (TCRE). A total of 263 women were treated by endometrial ablation, 129 randomized to MEA, 134 to TCRE. Inclusion criteria were any patient experiencing heavy menstrual loss and referred for endometrial ablation by their physician, including the allowance of fibroids and irregular cavities in both the treatment and control arm. Each subject received goserelin 3.6mg 5 weeks prior to treatment for endometrial preparation. Follow-up took place at 4 months, 12 and 24 months. Questionnaires addressed menstrual status, satisfaction, acceptability, and the need for additional intervention. After two years, 95% of women treated completed follow-up questionnaires. Menstrual bleeding and quality of life scores were similar in both groups. The satisfaction rate and amenorrhea rate was higher after MEA treatment. The rate of hysterectomy after two years was similar for both groups.

Effectiveness at One & Two Years Aberdeen Royal Infirmary Study

	12 Months		**24 Months**	
	MEA N=129	**TCRE n=134**	**MEA n=120**	**TCRE n=129**
Amenorrhea rate	40%	40%	47%	41%
Satisfaction rate	77%	75%	79%	67%
Acceptability rate	94%	90%	96%	88%
Hysterectomy rate			11.6%	12.7%

Principle of Operation

Once the physician determines that a patient is an appropriate candidate for the ablation procedure with MEA, the patient should be given a dose of medication (e.g. Lupron) to thin the lining of the uterus approximately three weeks prior to the procedure. During use, the Applicator is inserted into the uterine cavity until the Applicator tip reaches the fundus. The coaxial cable carries the microwave energy from the microwave generator to the reusable Applicator. The microwave energy is applied by depressing the footswitch connected to the control unit. Microwave energy emanates semi-radially from the Applicator tip and is absorbed by the surrounding endometrial tissue. The Applicator is moved slowly from side to side in the fundal area while observing and remaining within the target treatment temperature range (70-80 °C). Once the fundal area is completely treated, the treatment is continued with side-to-side movements while simultaneously withdrawing the Applicator from the uterine cavity. A Data Cable connected to the Applicator transmits temperature measurements from the Applicator tip and surrounding endometrial tissue to a color display providing the physician with real-time visual feedback of the treatment temperature. The microwave energy heats the endometrium, causing the temperature to rise. Likewise, when the Applicator tip is moved to an untreated area, the temperature falls. The physician uses this graphical response to control the depth and coverage of heating during the MEA treatment. The system achieves endometrial ablation by heating a 5-6 mm layer of intrauterine tissue to therapeutic temperature levels for the duration of the treatment, which averages 3 ½ minutes for the normal size uterus (75-85 mm, respectively). When the Applicator tip reaches the cervix the footswitch is released, which deactivates the microwave energy and the Applicator is fully withdrawn.



MEA Treatment Representation

Overview of the MEA Procedure

Pre-treatment

?? Prior to the operative day, an ultrasound evaluation is conducted to evaluate the uterine wall thickness.
?? Anesthetize and perform a bimanual examination of the patient.
?? Sound and dilate the uterus.
?? Confirm cavity integrity using hysteroscopy.
?? Further dilate the uterus, if required.

Following the instruction on the touch screen display:

MEA System Set-up

?? Input patient identification (i.e. name, number, etc.) information
?? Input sound measurement
?? Connect the applicator to the MEA system cables.

Applicator positioning

?? Insert the applicator to the correct cavity length, at which point light contact against the fundus should be felt
?? Confirm the applicator placement measurement is the same as the sounding measurement

Fundal treatment

?? Depress the Foot Switch to energize the microwave energy holding still the applicator in the mid-line fundal position for five seconds. At approximately 6 seconds, begin fundal sweeping with a gentle side-to-side movement, avoiding forward movements of the applicator.
?? Continue to treat the fundus with lateral sweeping movements of the applicator until the temperature has reached 70 ºC.

Cornual treatment

?? Gently position the applicator into the left cornual area
?? Once temperature begins to rise, the cornu is being treated and the applicator should be advanced to the right cornu.
?? Monitor the applicator tip temperature feedback (expect drop in temperature when moved and hold the applicator still until temperature recovers to midline or levels out in the temperature band)

Applicator movements

?? Continue with gentle sweeping movements constantly while withdrawing the applicator in half-centimeter increments.
?? Temperature should be maintained in the treatment band between 70-80 ?C

End of treatment

?? When the yellow band on the applicator is visible at the external cervical os, this is indication that the treatment is near completion.

?? Once the black band is seen at the external cervical os, treatment is complete and footswitch must be release.

?? Withdraw the applicator.

MULTI-CENTER CLINICAL TRIAL (PMA)

Primary Evaluation Parameters - Efficacy at One Year

Patient success was based on a reduction in diary score from a pretreatment score of =185 to =75 at one year post therapy. Amenorrhea is defined as a diary score of zero at one year.

The table below presents Intent-to-Treat success and amenorrhea rates. There were 13 MEA patients and 9 REA (control) patients missing or lost to follow-up. These patients were considered treatment failures in calculating success rates. Chi-square analysis reveals no statistical difference between the two groups in the Intent-to-Treat analysis.

Success Rates at One Year – Intent-to-Treat

	MEA n=215	**REA n=107**	**p-Value**
Successful patients [(1)]	187	89	
Success rate	**87.0%**	**83.2%**	0.359
Amenorrhea patients [(2)]	119	49	
Amenorrhea rate	**55.3%**	**45.8%**	0.106

This table presents Intent-to-Treat success rates. Seven patients (6 MEA and 1 REA) were not treated on the operative day. 13 MEA patients and 9 REA (control) patients were lost to follow up. Three additional subjects (2 MEA & 1 REA) did complete the 12 month visit; however a diary score was not available. These patients were considered failures in calculating success rates. Success is defined as a diary score of = 75. Amenorrhea is defined as a diary score of zero (0).

Success and Amenorrhea Rates with Fibroid Presence

Approximately 22% of the patients entered into the study had fibroids that did not exceed 3 cm in diameter, protruding into the uterine cavity. A subgroup analysis of the rate of treatment success for patients with fibroids and without fibroids is shown below.

Success Rates of Patients with Fibroids at One Year Intent-to-Treat

	MEA n=215	**REA n=107**	**p-Value**
Number of patients with fibroids	41	30	
Number of successful patients	28	23	
Success rate	**68.3%**	**76.7%**	0.594
Number of patients without fibroids	174	77	
Number of successful patients	159	66	
Success rate	**91.4%**	**85.7%**	0.183

This table presents Intent-to-Treat success rates. Seven patients (6 MEA and 1 REA) were not treated on the operative day. 13 MEA patients and 9 REA (control) patients were lost to follow up. Three additional subjects (2 MEA & 1 REA) did complete the 12 month visit; however a diary score was not available. These patients were considered failures in calculating success rates. Success is defined as a diary score of = 75.

Success Rates of Patients with Fibroids at One Year Evaluable Patients

	MEA n=194	REA n=96	p-Value
Number of patients with fibroids	31	26	
Number of successful patients	28	23	
Success rate	**90.3%**	**88.5%**	1.000
Number of patients without fibroids	163	70	
Number of successful patients	159	66	
Success rate	**97.5%**	**94.3%**	0.246
Evaluable patient population does not include those patients not treated or lost to follow. In addition, the three subjects (2 MEA & 1 REA) who completed the 12 month visit, but for whom a diary score was unavailable, are not included in the success analysis. Success is defined as a diary score of = 75			

Amenorrhea Rates of Patients with Fibroids at One Year Evaluable Patients

	MEA n=194	REA n=96	p-Value
Number of patients with fibroids	31	26	
Number of amenorrhea patients	19	10	
Amenorrhea rate	61.3%	38.5%	0.113
Number of patients without fibroids	163	70	
Number of amenorrhea patients	100	39	
Amenorrhea rate	61.3%	55.7%	0.467
Evaluable patient population does not include those patients not treated or lost to follow. In addition, the three subjects (2 MEA & 1 REA) who completed the 12 month visit, but for whom a diary score was unavailable, are not included in the success analysis. Amenorrhea is defined as a diary score of zero (0).			

Secondary Evaluation Parameters - Quality of Life

Patients before treatment and at 3,6, and 12 months post-treatment completed follow-up and Quality of Life (Short Form–36) questionnaires. Additional information was collected directly from patients during follow-up visits by investigators or site coordinators.

The form is scored such that 8 scale scores are given: physical functioning, bodily pain, general health perception, vitality, social functioning, emotional and mental health. Two summary measures can be calculated from these scales; called the physical component score and the mental component score. These two component scores at pre-treatment and 12-months post-treatment for both groups are provided in the table below along with the results of additional data collected by the investigators. Statistical analyses show no differences between the two study groups.

Quality of Life Data at One Year –Patient Satisfaction Evaluable Patients

	MEA n (%)	REA n (%)	p-Value
Number of patients responding	196	97	
Acceptance of operation			
Positive	194 (99.0%)	97 (100.0%)	1.000
Negative	2(1.0%)	0 (0%)	
Overall treatment satisfaction			
Very satisfied / Satisfied	193 (98.5%)	96 (99.0%)	1.000
Dissatisfied	3 (1.5%)	1 (1.0%)	
Dysmenorrhea			
Pre-treatment	176 (89.8%)	86 (88.7%)	0.841
Post-treatment	66 (33.6%)	33 (34.0%)	0.767
Evaluable patient population does not include those patients not treated or lost to follow. The three subjects (2 MEA & 1 REA) who completed the 12 month visit, but for whom a diary score was unavailable, are included in the quality of life analysis.			

Quality of Life Data at One Year –Short Form 36 Scores Evaluable Patients

	MEA n (%)	REA n (%)	p-Value
Number of patients responding Pre	208	102	
Number of patients responding Post	193	97	
SF-36 Scores: Physical component			
Pre-treatment	47.1 ± 9.22	46.5 ±8.1	0.576
Post-treatment	54.1 ± 6.6	53.6 ± 6.9	0.568
SF-36 Scores: Mental component			
Pre-treatment	46.5 ± 11.5	46.6 ± 11.4	0.926
Post-treatment	52.2 ± 9.1	51.5 ± 9.7	0.506
Evaluable patient population does not include those patients not treated or lost to follow. The three subjects (2 MEA & 1 REA) who completed the 12 month visit, but for whom a diary score was unavailable, are included in the quality of life analysis. Quality of Life scores range from 0-100 (worst to best).			

Anesthesia and Anesthesia Time

The clinical protocol did not specify the type of anesthesia to be used in both treatment groups and the decision of which type of anesthesia to use was left up to the discretion of the physician and patient preference. The table below shows the number of patients receiving which type of anesthesia for each treatment group.

Anesthesia Use

Anesthesia Type	MEA n=209	REA N=106
General	44.5% (93/209)	78.3% (83/106)
IV Sedation	54.1% (113/209)	16.0% (17/106)
Regional	0.5% (1/209)	3.8% (4/106)
IV Sedation plus regional	1.0% (2/209)	1.9% (2/106)

Anethesia Time

The total time that anesthesia was administered to each patient was determined. The table below shows the mean anesthesia time for both treatment groups. The mean anesthesia time for the MEA treatment group was significantly less than the mean anesthesia time for the REA group.

Anesthesia Time

	MEA n=209	REA n=106	p-Value
Mean (minutes)	39.26	47.10	0.007
Std. Deviation (minutes)	25.44	23.40	

Procedure Time

The time to complete treatment was determined for each patient by recording the time of device activation. The table below shows the mean procedure time for both treatment groups. The mean procedure time for MEA treatment group was significantly less than the mean procedure time for the REA group.

Procedure Time

	MEA n=209	REA n=106	p-Value
Mean (minutes)	3.45	20.26	0.000
Std. Deviation (minutes)	1.02	15.60	